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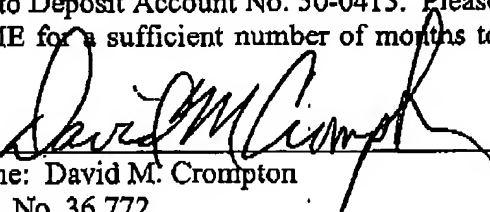
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In re: Lixiao Wang Confirmation No.: 2784
Serial No.: 10/027,417 Examiner: R. Maiorino
Filing Date: December 20, 2001 Group Art Unit: 3763
Docket No.: 1001.1461101 Customer No.: 28075
For: CATHETER HAVING AN IMPROVED BALLOON-TO-CATHETER BOND

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APPEAL BRIEF UNDER 37 C.F.R. § 1.192

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Dear Sir:

Pursuant to 37 C.F.R. § 1.192, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on November 15, 2004. As indicated on the Fax Cover Letter, please charge the fee prescribed by 37 C.F.R. § 1.17(c) in the amount of \$500.00 to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Mail Stop A150, Maple Grove, Minnesota 55311-1566. An assignment from the inventor, Lixiao Wang, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 012413, Frame 0603.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-22 are cancelled. Claims 23-38 remain pending. Claims 23-26, 29-32 and 35-38 stand rejected under 35 U.S.C. §102(b) based on U.S. Patent No. 5,876,376 to Schwab et al. Claims 29 and 33-34 stand rejected under 35 U.S.C. §102(b) based on U.S. Patent No. 6,706,010 to Miki et al. Claim 29 stands rejected under 35 U.S.C. §102(b) based on U.S. Patent No. 5,176,698 to Burns et al. Claim 29 stands rejected under 35 U.S.C. §102(b) based on U.S. Patent No. 6,375,367 to Campbell et al. Claims 27-28 stand rejected under 35 U.S.C. §103(a) based on Schwab et al. in view of Miki et al. Each rejection of claims 23-38 is appealed herein.

IV. STATUS OF AMENDMENTS

Amendments and remarks dated 04/15/2003, 11/13/2003, 01/13/2004, 05/04/2004 and 09/03/2004 have been entered and considered.

V. SUMMARY OF CLAIMED SUBJECT MATTER¹

The present invention relates to catheters. More particularly, the present invention relates to balloon catheters having improved distal balloon attachment. An illustrative balloon catheter design includes a catheter having a balloon disposed near its distal end, with the catheter including an outer tube and an inner tube at least at a location just proximal of the balloon. The inner tube defines a guidewire lumen, and the space between the inner and outer tubes defines an inflation lumen in communication with the interior of the balloon. The balloon is attached at its

¹ The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

proximal end to the outer tube, and at its distal end to the inner tube. The desired material characteristics for the balloon, the outer tube, and the inner tube may differ, such that constructions using different materials for at least one of the tubes and the balloon are sometimes desired, which can make attachment of the balloon to either tube difficult. The present invention is directed at improving the bonding between the balloon and a tubular member. As seen in Figure 3, a tie member is placed between the balloon 28 and the inner tube 22. As shown in Figure 4, the tie member 40 is provided as a separate tubular member, and may, if desired, include multiple layers 34, 36.

Turning now to the claims, independent claim 23 recites a balloon catheter (Figure 1, element 10; Specification at page 4, line 21, to page 5, line 3) comprising an outer tubular member (Figure 1, element 26; Specification at page 5, line 21 to page 6, line 14) having a distal end region; an inner tubular member (Figures 1-3, element 22; Specification at page 6, line 15 to page 7, line 4) disposed within the outer tubular member (Specification at page 5, line 21 to page 6, line 1), the inner tubular member having a distal end region that extends distally from the distal end region of the outer tubular member (the outer tubular member does not extend to the distal end of the balloon as shown in Figure 3, while the inner tubular member does); a balloon (Figure 1, element 14; Specification at page 7, lines 5-19; Specification at page 8 lines 1-3) having a proximal portion (Figure 1, element 30) and a distal portion (Figure 1, element 32), the proximal portion being attached to the distal end region of the outer tubular member (Figure 1 shows element 30, the balloon proximal portion, secured to element 26, the outer tubular member) and the distal portion being attached to the distal end region of the inner tubular member (Figure 1 and 3 show element 32, the balloon distal portion, attached to element 22, the inner tubular member), wherein the distal portion of the balloon defines a distal waist having a distal waist length. Claim 23 further recites a tie layer (Specification at page 10, lines 3-23) defined by a heat shrink tubular member (Specification at page 10, lines 18-20) that is disposed between the distal waist of the balloon and the distal end region of the inner tubular member (Specification at page 10, lines 7-9; also shown in Figures 3-4 with tie layer member 40 comprising layers 34, 36 between balloon distal waist 32 and inner member 22); the heat shrink tubular member being heat shrunk to the inner tubular member (Specification at page 10, lines 18-20; Specification at page 11, lines 14-20) and being thermally bonded to the distal waist of the balloon (Specification at page 11, lines 14-20; Specification at page 12, lines 22-23), the tie

layer having a length that is substantially the same as the distal waist length (Specification at page 12, line 23, to page 13, line 2; also shown in Figure 3).

Dependent claim 24 recites a balloon catheter of claim 23, wherein the tie layer includes low density polyethylene (Specification at page 10, lines 17-18). Dependent claim 25 recites a balloon catheter of claim 23, wherein the tie layer is heat-shrunk onto the inner tubular member (Specification at page 10, lines 18-20). Dependent claim 26 recites a balloon catheter of claim 23, wherein the tie layer is multi-layered (Specification at page 11, line 21, to page 12, line 15; Specification at page 13, lines 6-14 and lines 20-21; multiple layers are shown in Figures 3 and 4). Dependent claim 27 recites a balloon catheter of claim 23, wherein the inner tubular member includes polyethylene (Specification at page 6, lines 16-17) and wherein the tie layer has a relatively high bonding affinity for polyethylene (Specification at page 10, lines 12-15). Dependent claim 28 recites a balloon catheter of claim 23, wherein the inner tubular member includes polytetrafluoroethylene (Specification at page 6, lines 17-19) and wherein the tie layer has a relatively high bonding affinity for polytetrafluoroethylene (Specification at page 10, lines 12-15).

Independent claim 29 recites a balloon catheter (Figure 1, element 10; Specification at page 4, line 21 to page 5, line 3), comprising a first tubular member having a distal end region (Figure 1, element 26; Specification at page 5, line 21 to page 6, line 14); a second tubular member (Figures 1-3, element 22; Specification at page 6, line 15 to page 7, line 4) disposed within the first tubular member (Specification at page 5, line 21 to page 6, line 1), the second tubular member having a distal end region that extends distally from the distal end region of the first tubular member (the outer tubular member does not extend to the distal end of the balloon as shown in Figure 3, while the inner tubular member does); a balloon (Figure 1, element 14; Specification at page 7, lines 5-19; Specification at page 8, lines 1-3) having a proximal portion (Figure 1, element 30) and a distal portion (Figure 1, element 32), the proximal portion being attached to the distal end region of the first tubular member (Figure 1 shows element 30, the balloon proximal portion, secured to element 26, the outer tubular member, near its distal end) and the distal portion being attached to the distal end region of the second tubular member (Figures 1 and 3 show element 32, the balloon distal portion, secured to element 22, the inner tubular member), wherein the distal portion of the balloon defines a distal waist having a distal waist length. Claim 29 further recites a tie layer insert (Specification at page 10, lines 3-23,

Figure 4, element 40; Specification at page 11 line 21 to page 12, line 15) disposed between and thermally bonded to both the distal waist of the balloon and the distal end region of the second tubular member (Specification at page 11, lines 14-20; Specification at page 12, lines 22-23), the tie layer insert having a length that is substantially the same as the distal waist length Specification at page 12, line 23 to page 13, line 2; also shown in Figure 3).

Dependent claim 30 recites the balloon catheter of claim 29, wherein the tie layer insert includes low density polyethylene (Specification at page 10, lines 17-18). Dependent claim 31 recites the balloon catheter of claim 29, wherein the tie layer insert is heat-shrunk onto the second tubular member (Specification at page 10, lines 18-20). Dependent claim 32 recites the balloon catheter of claim 29, wherein the tie layer insert includes a plurality of layers (Specification at page 11, line 21, to page 12, line 15; Specification at page 13, lines 6-14 and lines 20-21; multiple layers are shown in Figures 3 and 4). Dependent claim 33 recites the balloon catheter of claim 29, wherein the second tubular member includes polyethylene (Specification at page 6, lines 16-17) and wherein the tie layer has a relatively high bonding affinity for polyethylene (Specification at page 10, lines 12-15). Dependent claim 34 recites the balloon catheter of claim 29, wherein the second tubular member includes polytetrafluoroethylene (Specification at page 6, lines 17-19) and wherein the tie layer has a relatively high bonding affinity for polytetrafluoroethylene (Specification at page 10, lines 12-15).

Independent claim 35 recites a balloon catheter (Figure 1, element 10; Specification at page 4, line 21 to page 5, line 3), comprising an outer tubular member (Figure 1, element 26; Specification at page 5, line 21 to page 6, line 14) having a distal end region; an inner tubular member (Figures 1-3, element 22; Specification at page 6, line 15 to page 7, line 4) disposed within the outer tubular member (Specification at page 5, line 21, to page 6, line 1), the inner tubular member having a distal end region that extends distally from the distal end region of the outer tubular member (the outer tubular member does not extend to the distal end of the balloon, as shown in Figure 3, while the inner tubular member does); a balloon (Figure 1, element 14; Specification at page 7, lines 5-19; Specification at page 8, lines 1-3) having a proximal portion (Figure 1 element 30) and a distal portion (Figure 1, element 32) having a length, the proximal portion being attached to the distal end region of the outer tubular member (Figure 1 shows element 30, the balloon proximal portion, secured to element 26, the outer tubular member) and

the distal portion being attached to the distal end region of the inner tubular member (Figures 1-3 show element 32, the balloon distal portion, attached to element 22, the inner tubular member); and a multi-layer insert (Specification at page 11, line 21, to page 12, line 15; Specification at page 13, lines 6-14 and lines 20-21; multiple layers are shown in Figures 3 and 4) disposed between the distal portion of the balloon and the distal end region of the inner tubular member (Specification at page 10, lines 7-9; also shown in Figures 3-4 with tie layer member 40 comprising layers 34, 36 between balloon distal waist 32 and inner member 22), the multi-layer insert having a length that is substantially the same as the length of the distal portion of the balloon (Specification at page 12, line 23 to page 13, line 2; also shown in Figure 3).

Independent claim 36 recites method for bonding a balloon to a catheter shaft, the method comprising the steps of providing a catheter shaft (Figure 1 shows shaft 12), the catheter shaft including an outer tubular member with a distal end region (Figure 1, element 26; Specification at page 5, line 21 to page 6, line 14) and an inner tubular member (Figures 1-3, element 22; Specification at page 6, line 15 to page 7, line 4) disposed within the outer tubular member (Specification at page 5, line 21 to page 6, line 1), the inner tubular member having a distal end region that extends distally from the distal end region of the outer tubular member (the outer tubular member does not extend to the distal end of the balloon, as shown in Figure 3, while the inner tubular member does); providing a tie layer having a length (Figures 3 and 4 illustrate a tie layer; Specification at page 10, lines 3-23); thermally bonding the tie layer onto a portion of the distal end region of the inner tubular member (page 10, lines 18-20; page 11, lines 14-20; page 12, lines 22-23); providing a balloon having a proximal waist, a distal waist, and an expandable region therebetween (Figure 1, balloon 14, proximal waist 30, distal waist 32, expandable region 28; Specification at page 7, lines 5-19; Specification at page 8, lines 1-3), the distal waist having a length that is substantially the same as the length of the tie layer (Specification at page 12, line 23 to page 13, line 2; also shown in Figure 3); and affixing the distal waist of the balloon to tie layer (Specification at page 11, lines 14-20; page 12, lines 22-23).

Dependent claim 37 recites the method of claim 36, wherein the step of thermally bonding the tie layer onto a portion of the distal end region of the inner tubular member includes heat shrinking the tie layer onto a portion of the distal end region of the inner tubular member (Specification at page 10, lines 18-20; page 11, lines 14-20). Dependent claim 38 recites the method of claim 36, wherein the step of affixing the distal waist of the balloon to tie layer

includes thermally bonding the distal waist of the balloon to the tie layer (Specification at page 11, lines 14-20; page 12, lines 22-23).

VI. GROUNDS OF REJECTION TO BE REVEALED ON APPEAL

Whether claims 23-26, 29-32, and 35-38 are patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 5,876,376 to Schwab et al.

Whether claims 29 and 33-34 are patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 6,706,010 to Miki et al.

Whether claim 29 is patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 5,176,698 to Burns et al.

Whether claim 29 is patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 6,375,367 to Campbell et al.

Whether claims 27-28 are patentable over the 35 U.S.C. §103(a) rejection based on Schwab et al. in view of Miki et al.

VII. ARGUMENT

A. Claims 23-26, 29-32, and 35-38 are patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 5,876,376 to Schwab et al.

1. *Claims 23-25*

Schwab et al. disclose a balloon catheter using adhesive to bond a balloon to outer and inner shafts. Schwab et al. identifies problems with the use of adhesives for this purpose:

Concentric bonding of coaxial shafts often result in eccentric, inconsistent bonds which can result in bond failure. Some devices use a manufacturing fixture to align the coaxial shafts. External fixtures typically hold the outer diameters of the two shafts and insert one into the other. Shaft diameter, wall thickness and concentricity variation can still result in inconsistent bonds.

Adhesives may wick past the end of the shaft into an unintended lumen. To remedy this some adhesive bonds are lengthened to minimize the chance of the adhesive wicking past the end of the lumen. The presence of an elongated stiff section of adhesive can be a disadvantage with respect to catheter flexibility and trackability. The shorter the bond the easier it is to negotiate a torturous path. What is needed is a balloon bond which minimizes bond length and thereby optimizes flexibility as well as withstands internal pressure of at least 500 psi

shafts which results in a uniform concentric alignment. The "positive stop" provided by a stopper is important to obtain a uniform gap into which adhesive can be dispensed. The invention also serves to stop the flow of adhesive past a defined point which is critical in balloon bonding since the presence of adhesive in the balloon/shaft area can adversely affect balloon in/deflation and balloon burst strength. A setback between the stopper and the end of the balloon cone increases the burst strength of the balloon and is necessary for high pressure balloons.

(Schwab et al. at column 2, line 62 to column 3, line 7).

Going further into the relative sizes, Schwab et al. state, "The balloon 35 necks are trimmed to between approximately 1.5 mm to 4.0 mm at the proximal and distal ends." (Schwab et al. at column 3, lines 23-25). Then, Schwab et al. note "The stoppers 30, 50 should be trimmed to a length of approximately 0.5 mm plus or minus 0.25 mm". (Schwab et al. at column 5, lines 12-14). Therefore, the balloon necks are between three and eight times as long as the adhesive stoppers. Meanwhile, the length in which the adhesive extends beneath the balloon necks (balloon tails 75, 85) is, at most (assuming no setback though such is suggested by Schwab et al.), 1.0 mm out of 1.5 mm, or 3.5 mm out of 4.0 mm. Respectively this is between 67 and 88 percent of the length of the balloon waists for the length of the adhesive portions.

Claim 23 recites, in relevant part:

a tie layer defined by a heat shrink tubular member that is disposed between the distal waist of the balloon and the distal end region of the inner tubular member, the heat shrink tubular member being heat shrunk to the inner tubular member and being thermally bonded to the distal waist of the balloon, the tie layer having a length that is substantially the same as the distal waist length.

Thus, a heat shrink tubular member defines a tie layer between the distal balloon waist and the distal end region of the inner tubular member. Importantly, the heat shrink tubular member/tie layer has a length that is substantially the same as the distal waist length for the balloon. This is a single element having substantially the same axial length as the distal balloon waist.

As noted above, the rejections are rather generic, leaving Appellants to determine which disclosed elements of Schwab et al. are asserted as corresponding to the recited claim elements. It appears to Appellant that the only available disclosed elements in Schwab et al. which could plausibly read on the recited tie layer are the distal stopper 50 or the distal adhesive 10. However, neither has a length corresponding to that which is recited, and therefore neither meets the claim language. Within the context of §102, the stopper 50 and adhesive 10 cannot be read

as a single element, as that is not how they are disclosed (indeed Schwab et al. appears to suggest using different materials for each in several embodiments). Therefore, at least one recited element of claim 23 is not disclosed.

In light of the above remarks, independent claim 23 and dependent claims 24-25 are believed to be patentable over Schwab et al.

2. *Claim 26*

Claim 26 recites:

26. The balloon catheter of claim 23, wherein the tie layer is multi-layered.

Appellant notes that claim 26 requires a multi-layered element for the tie layer. In addition to the reasons given above with reference to claim 23, Appellant believes that the multi-layered recitation of claim 26 is not disclosed by Schwab et al. The Examiner has not identified such disclosure in Schwab et al. Section 102 requires disclosure of each and every element of the claim. Therefore, claim 26 is believed to be further patentable over Schwab et al.

3. *Claims 29-31*

Claim 29 recites, in relevant part:

a tie layer insert disposed between and thermally bonded to both the distal waist of the balloon and the distal end region of the second tubular member, the tie layer insert having a length that is substantially the same as the distal waist length.

It is noted that a single tie layer insert – one element – is recited in claim 29. The insert must have a length that is substantially the same as the length of the distal waist of the balloon. As illustrated above, Schwab et al. merely discloses a first insert (the stopper) and a length of adhesive. Both are provided beneath the balloon waist, meaning neither can have the same length as the balloon waist. Because a single element is not disclosed having the recited features of claim 29, claim 29 is not anticipated by Schwab et al.

In light of these remarks, each of claims 29-31 is believed to be patentable over Schwab et al.

4. *Claim 32*

Claim 32 recites:

32. The balloon catheter of claim 29, wherein the tie layer insert includes a plurality of layers.

Appellant notes that claim 32 requires a plurality of layers in the tie layer insert. In addition to the reasons given above with reference to claim 29, Appellant believes that the plurality of layers recitation of claim 32 is not disclosed by Schwab et al. The Examiner has not identified such disclosure in Schwab et al. Section 102 requires disclosure of each and every element of the claim. Therefore, claim 32 is believed to be further patentable over Schwab et al.

5. *Claim 35*

Claim 35 recites, in relevant part:

a multi-layer insert disposed between the distal portion of the balloon and the distal end region of the inner tubular member, the multi-layer insert having a length that is substantially the same as the length of the distal portion of the balloon.

Thus there is a multi-layer structure defined between the balloon and the inner tubular member. As explained above, Schwab et al. suggest a stopper and a single adhesive. Claim 35 thus defines over the single adhesive, which would not be a multi-layer piece. As Appellant has explained in the specification:

In certain embodiments, both the first layer 34 and the second layer 36 may comprise tie layer materials. For example, the first tie layer 34, because of its positioning, may possess a greater bonding affinity to materials forming a distal balloon waist 32. Whereas the second tie layer 36 may possess a greater bonding affinity to materials forming an inner tubular member 22. Although either the first 34 or the second 36 tie layer may possess a bonding affinity to both the distal balloon waist 32 and the inner tubular member 22, the layer distribution as described may provide the maximum bonding efficiency for the region as a whole.

(Specification at page 12, lines 8-15).

Although in the Final Office Action, the Examiner makes mention of "a tie layer (5 & 30) that is multiplayer [sic] and is defined by a heat shrink tubular member", Appellant can find no such disclosure in Schwab et al. Therefore, at least one recited element of claim 35 is not disclosed in the cited reference. As such, claim 36 is patentable over Schwab et al.

6. *Claim 36*

Claim 36 recites, in full:

36. A method for bonding a balloon to a catheter shaft, the method comprising the steps of:

providing a catheter shaft, the catheter shaft including an outer tubular member with a distal end region and an inner tubular member disposed within the outer tubular member, the inner tubular member having a distal end region that extends distally from the distal end region of the outer tubular member;

providing a tie layer having a length;

thermally bonding the tie layer onto a portion of the distal end region of the inner tubular member;

providing a balloon having a proximal waist, a distal waist, and an expandable region therebetween, the distal waist having a length that is substantially the same as the length of the tie layer; and

affixing the distal waist of the balloon to tie layer.

Appellant notes that in the Office Action, the Examiner has not specifically addressed any of the above steps, including providing a tie layer having a length, thermally bonding the tie layer onto the inner tubular member, providing a balloon having a distal waist with a length substantially the same as the length of the tie layer, and affixing the distal waist of the balloon to the tie layer.

After careful review of Schwab et al., the following appears to be the most relevant portion of the cited reference for analyzing claim 36:

If a heat shrinkable material is used for stoppers 30, 50 such as PE, heat shrink the stoppers 30, 50 using any conventional means. Adhesive stoppers may be less preferred than heat shrinkable stoppers if the adhesive viscosity is such that it creates the potential for adhesive migration before the adhesive dries. To reduce the likelihood of adhesive migration, adhesives with a viscosity which approaches a gel are preferred.

(Schwab et al. at column 4, lines 34-42). Appellant notes that the adhesive (5, 10) is provided and allowed to flow or wick into place. The stoppers are substantially shorter (0.5 mm) than the balloon waists (1.5 mm to 4.0 mm) disclosed by Schwab et al. There is no indication that the distal waist of the balloon is secured to the stopper. Instead, adhesive is applied separately to secure the distal balloon waist to the inner tube, with the stopper merely preventing flow of the adhesive past a desired point.

In light of the above, several steps recited in claim 36 have not been addressed by the Examiner and are not disclosed by Schwab et al. Therefore, claim 36 is believed to be patentable over Schwab et al.

7. *Claim 37*

Claim 37 recites:

37. The method of claim 36, wherein the step of thermally bonding the tie layer onto a portion of the distal end region of the inner tubular member includes heat shrinking the tie layer onto a portion of the distal end region of the inner tubular member.

Appellant notes that the tie layer, not merely a portion thereof, is heat shrunk onto the inner tubular member in the recited method of claim 37. Therefore, for the reasons stated with respect to claim 36, and further because Schwab et al. does not disclose heat shrinking a tie layer as recited (particularly having the recited length) onto the inner tube, claim 37 is believed to be patentable over Schwab et al.

8. *Claim 38*

Claim 38 recites:

38. The method of claim 36, wherein the step of affixing the distal waist of the balloon to tie layer includes thermally bonding the distal waist of the balloon to the tie layer.

As noted above with respect to claim 36, there is no disclosure in Schwab et al. that the distal waist of the balloon is thermally bonded to anything, let alone a tie layer as recited. Therefore, for the reasons stated with respect to claim 36, and further because the distal balloon waist of Schwab et al. is not thermally bonded to anything, claim 38 is believed to be patentable over Schwab et al.

B. Claims 29 and 33-34 are patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 6,706,010 to Miki et al.

With respect to Miki et al., the Examiner states a very general rejection, given the substantial length of the Miki et al. patent:

Miki teaches a balloon catheter with an outer tubular member and an inner tubular member and a balloon having a proximal and distal portion the proximal portion being attaches [sic] to the distal end region of the outer tubular member and the distal portion being attached to the distal end region of the inner tubular member a tie layer [sic].

(Final Office Action at Paragraph 2). On careful review of the lengthy disclosure of Miki et al., the most Appellant can determine is that the Examiner is referring to one or more of Figures 11, 12, 17, 18, and/or 21, and the text accompanying and/or describing these figures to provide a basis for the rejection.

Figures 11 and 12 show embodiments wherein an adhesive agent 21 is used to secure the distal balloon waist (described as sleeve 7) to an inner member. In either case, it is clearly disclosed that an adhesive agent is used, as described by Miki et al., and not a tie layer.

Figures 17 and 18 show distal adhesive portions 60, 61. Miki et al. explain Figures 17 and 18:

There are no particular restrictions on the composition or chemical structure of the above-mentioned two-liquid normal temperature (room temperature) curing adhesive agent, UV curing adhesive agent, and water-absorption curing adhesive agent. Specifically, a common urethane, epoxy, or silicone type of adhesive agent comprising a mixture of a main component and a curing agent can be used as a two-liquid room temperature curing adhesive agent, and a cyanoacrylate-based adhesive agent, a single-liquid curing urethane adhesive agent, or the like can be used as a water-absorption curing adhesive agent.

There are no particular restrictions on the method for applying the adhesive agent, but it is preferable for the balloon portion after bonding to be as shown in FIGS. 17 and 18, and particularly as in the above-mentioned FIGS. 11 and 12. In FIG. 17, 4 is the outer tube of a catheter shaft 1 comprising a double-tube, 5 is the inner tube of the catheter shaft 1 comprising a double-tube, 3 is a balloon, 60 is an adhesive agent applied to the joined portions of the outer tube 4 and the sleeve 6 on the proximal side, 61 is an adhesive agent applied to the joined portions of the inner tube 5 and the sleeve 7 on the distal side, and 62 is an X-ray impermeable marker provided to the inner tube 5 in the interior of the balloon 3. FIG. 18 shows a structure in which adhesive agents 63 and 64 have been built up on the sleeves 6 and 7 of the balloon 3, which reduces the discontinuity in rigidity and the step between the inner tube 5 and outer tube 4 and the balloon 3.

The adhesive agent may be applied by a method in which a suitable amount of adhesive agent is used to coat the joined portions of the outer tube 4 and inner tube 5 of the catheter shaft 1 ahead of time, after which the catheter shaft and the balloon are assembled, or the catheter shaft and balloon may be assembled and the adhesive agent then allowed to flow into the joined portions of the outer tube 4 and inner tube 5 of the catheter shaft 1. The effect of the present invention is not limited by using another method besides the above to apply the adhesive agent.

(Miki et al. at column 21, line 61, to column 22, line 31). A liquid adhesive is used and applied, rather than a tie layer insert.

Figure 21 is explained as follows:

FIG. 21 is an enlarged cross section illustrating the very farthest point at the distal end portion of a balloon catheter. In the figure, 100 is a balloon and 101 is an inner tube. The inner tube 101 goes through and sticks out from the distal end portion of the balloon 100, and is bonded to the distal end-side bonded portion of this balloon by an adhesive agent layer 103. The distal end portion of the inner tube 101 retains the tubular shape of the inner tube, and has an edge 104 at the most distal end portion. A problem with this edge 104, however, was that it would snag when passing through the afflicted site in a blood vessel or through a curved section, making it difficult to pass the catheter through these areas.

(Miki et al. at column 2, lines 51-63). Again, the adhesive agent layer is disclosed.

Claim 29 recites, in relevant part:

a tie layer insert disposed between and thermally bonded to both the distal waist of the balloon and the distal end region of the second tubular member, the tie layer insert having a length that is substantially the same as the distal waist length.

As explained above, a liquid adhesive is applied in each of the shown examples, and there is no tie layer insert shown. Nor is there thermal bonding. As Appellant has explained:

Success in bonding the distal balloon waist 32 to the inner tubular member 22 or the proximal waist 30 to the outer tubular member 26 has been traditionally achieved using an adhesive. In these traditional methods, the adhesive is first applied between the two components. The two components are then bonded together to form the completed sealed union. There exist drawbacks, however, to using adhesives in such bonding procedures. For example, adhesives that are suitable for joining the two catheter components are commonly associated with long curing times, sensitivity to ambient conditions (including humidity and temperature), and the need for extensive surface treatment. As a result, bonding between the distal balloon waist 32 and the inner tubular member 22 and the proximal balloon waist 30 and outer tubular member 26 is typically time and labor intensive.

(Specification at page 9, lines 7-17). Thus adhesives create several drawbacks.

The Examiner has roughly stated a product by process interpretation of the claims. However, as pointed out in the Schwab et al. patent, the end result of these processes is different. Specifically, the tie layer insert recited in claim 29, which is thermally bonded, is uncured. A cured adhesive is not a tie layer insert having the same predictable properties that a tie layer

insert has. As pointed out repeatedly in the Schwab et al. patent, above, the properties of an adhesive can be unpredictable because (at least without the spacer and adhesive blocker suggested by Schwab et al.) the annular space the adhesive must be injected/wicked into is not necessarily consistent. Maintaining the pieces in exact, concentric alignment during application of the adhesive is difficult. Preventing the liquid adhesive from escaping the desired bond area is also difficult. These difficulties reduce the reliability of the catheter thus produced, and increase the variance in catheter properties. In short, less is known about a catheter produced using an injected/wicked adhesive; repeatability, reliability, and specificity in production processes is a highly important characteristic of medical devices.

Thus, the device recited is different from one formed using the adhesives disclosed in the cited reference, in particular as explained by the Schwab et al. reference that has been cited by the Examiner. In light of the above, all aspects of the Miki et al. rejection are believed overcome.

C. Claim 29 is patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 5,176,698 to Burns et al.

The rejection is, again, quite general. As before, Appellant is left to determine what is meant. As best Appellant understands the rejection, one of element 135 (Figs. 9-10), the portions shown beneath 40 (Figures 1, 2 and 5), or the portions shown beneath element 86 (Figures 6-7) are supposed to correspond to the recited tie layer insert.

Burns et al. describe their catheter construction, with respect to the portion shown beneath 40 in Figures 1, 2 and 5:

The distal segment 40 of the balloon member 16 is bonded to a distal end of a second inner tube 42, also preferably by an adhesive such as an epoxy.

(Burns et al. at column 4, lines 17-19). With respect to the portion shown beneath element 86 in Figures 6-7, less specific description is given:

The balloon member 58 is preferably formed of a polymer material such as polyolefin copolymer and comprises a balloon lip segment 82, a distensible balloon segment 84 and a small diameter distal segment 86. The balloon lip segment 82 is attached to the distal waist segment 75 of the outer tube 74, preferably by an epoxy bond. The distensible balloon segment 84 extends distally from the balloon lip segment 82 coaxially disposed about the inner tube 70. The length of the inner tube 70 extending beyond the distal waist segment 75 of the

outer tube 74 is designed to coincide with the length of the balloon member 58 such that the small diameter distal segment 86 of the balloon member 58 is bonded to a distal end of the inner tube 70. The balloon member 58 is thus sealably secured to the outer tube 74 (proximally) and inner tube 70 (distally) to define a balloon cavity 87 therebetween. A balloon member inlet port 79 for the balloon cavity 87 is defined by the extension of the inflation lumen 80 therethrough. Thus, the balloon inflation port 78, the inflation lumen 80, and the balloon member inlet port 79 cooperate to provide a path for the inflation medium to the balloon member 58.

(Burns et al. at column 7, line 64, to column 18, line 17). No details for the distal balloon waist bond are given. With respect to element 135:

The balloon member 116 is affixed at the balloon lip segment 142 to the distal waist segment 140 of the outer tube 132 and at the distal segment 146 to the distal end 135 of inner tube 128, by an adhesive seal such as epoxy.

(Burns et al. at column 9, lines 60 to 64). In light of the above, each of the attachments shown does not include disclosure of a tie layer insert member as recited.

Appellant again focuses on the claim language:

a tie layer insert disposed between and thermally bonded to both the distal waist of the balloon and the distal end region of the second tubular member, the tie layer insert having a length that is substantially the same as the distal waist length.

Claim 29 recites a tie layer insert, thereby indicating that a discrete element exists. Burns et al. only disclose adhesive, rather than an insert. Therefore, the §102 rejection of claim 29 relying upon Burns et al. should be withdrawn.

Vague reference has been made to “product by process” claims. However, Schwab et al. (cited by the Examiner) indicates some of the shortcomings of the use of an adhesive, including, in particular, inconsistency in the shape and characteristics of the bond. The recited invention does not suffer these shortcomings, such that the resultant product is distinguishable over the cited reference when taken in view of the Examiner’s art.

D. Claim 29 is patentable over the 35 U.S.C. §102(b) rejection based on U.S. Patent No. 6,375,367 to Campbell et al.

Appellant notes that the Final Rejection makes reference to “U.S. Patent No. 3675367 to Campbell et al.” However, it appears this reference is a typographical error. Appellant believes

the intended reference is U.S. Patent No. 6,375,367 to Campbell et al. Again, because the rejection fails to specifically address claim elements individually and with reference to the cited patent, Appellant relies on conjecture to relate the claim to the reference. This task is made more difficult with respect to Campbell et al. because none of the Figures appear to show anything (adhesive layer or tie layer) between the balloon and the inner tube of the shown catheters. Instead, at least in the Figures, collars 18 and 19 appear to hold the balloon to the catheter. For example:

Preferably, as shown by FIG. 1, a binding or securing band 18 is used to secure the distal end 16 of the balloon 10 to the exterior surface of the catheter shaft 20. A similar binding or securing band 19 retains the proximal end of the balloon 10 to the exterior surface of the catheter shaft 20.

(Campbell et al. at column 5, lines 1-6). Campbell et al. make reference to adhesives in describing how the bands 18, 19 can be formed and secured to the exterior of the balloon for pinching the balloon onto the shaft, for example, as explained at column 3, lines 43-51 and column 5, lines 44-55.

Briefly, Campbell et al. note, "The same type of adhesive can be used between the exterior surface of the catheter shaft and the interior surface of the end of the balloon." Campbell et al. at column 6, lines 10-12. From the disclosure, it appears that there is no discrete or separate element disposed between the balloon and the inner tube of the catheter shaft.

Appellant again focuses on the claim language:

a tie layer insert disposed between and thermally bonded to both the distal waist of the balloon and the distal end region of the second tubular member, the tie layer insert having a length that is substantially the same as the distal waist length.

Claim 29 recites a tie layer insert, thereby indicating that a discrete element exists. Campbell et al. only disclose an adhesive, rather than an insert. Therefore, the §102 rejection of claim 29 relying upon Campbell et al. should be withdrawn.

The Examiner has vaguely referred to "product by process" claims. However, Schwab et al. (cited by the Examiner) indicates some of the shortcomings of the use of an adhesive, including, in particular, inconsistency in the shape and characteristics of the bond. The recited invention does not suffer these shortcomings, such that the resultant product is distinguishable over the cited reference when taken in view of the Examiner's art.

E. Claims 27-28 are patentable over the 35 U.S.C. §103(a) rejection based on Schwab et al. in view of Miki et al.

The rejection of claims 27-28 using Schwab et al. in view of Miki et al. states, "Schwab teaches the invention except for the tubes being made out of polyethylene and polytetrafluoroethylene." In short, Miki et al. is cited merely to provide materials for the catheter construction as recited. However, as noted above with respect to each of Schwab et al. and Miki et al., neither reference discloses a tie layer as recited in base claim 23. Combining the two references does not address this missing element from each. Therefore, the §103(a) rejection should be reversed.

F. The "product-by-process" Assertion

Appellant believes that the above remarks distinguish the claimed invention from each of the cited references. The Examiner has stated:

Applicant has amended claim 29 so the tie layer is thermally bonded however such a limitation is a product by process limitation. MPEP 2112.02 "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The general concept noted is not disputed by Appellant. However, its application to the present claims appears tenuous, at best, and has not been explained. More particularly, the recited insert and/or tie layer for several claims is not disclosed in any of the cited references. Indeed, the method of manufacture does not determine whether there is an insert or not, or whether an element is part of the catheter as recited. To the extent Appellant feels comfortable in his understanding of this aspect of the Final Office Action, it has been addressed in the above claims. However, some claims are method claims for which this passage is entirely irrelevant.

The Advisory Action mailed on November 4, 2004, makes further reference to this product-by-process assertion. Not only is the assertion inapplicable to the pending method claims, but it remains unclear what precisely is meant. While Appellant is capable of making educated guesses, this is not Appellant's duty. Instead, the burden of establishing a *prima facie*

case of unpatentability lies with the Examiner. The above comments addressing the "product-by-process" assertions should not be construed as admissions of any relationship between elements of the present invention and those of the cited references. The comments are made merely in the hopes of advancing prosecution.

Appellant requests that, if this assertion forms a part of the rejection, the assertion should be incorporated into the rejections and explained in a direct manner, enabling Appellant to make his own assessment of patentability and respond accordingly.

G. Conclusion

For the reasons stated above, the rejection of claims 1-21 under 35 U.S.C. §§102(e) and 103(a) should be reversed.

Respectfully submitted,

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By his attorney,



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VIII. CLAIMS APPENDIX

23. A balloon catheter, comprising:

an outer tubular member having a distal end region;

an inner tubular member disposed within the outer tubular member, the inner tubular member having a distal end region that extends distally from the distal end region of the outer tubular member;

a balloon having a proximal portion and a distal portion, the proximal portion being attached to the distal end region of the outer tubular member and the distal portion being attached to the distal end region of the inner tubular member;

wherein the distal portion of the balloon defines a distal waist having a distal waist length; and

a tie layer defined by a heat shrink tubular member that is disposed between the distal waist of the balloon and the distal end region of the inner tubular member, the heat shrink tubular member being heat shrunk to the inner tubular member and being thermally bonded to the distal waist of the balloon, the tie layer having a length that is substantially the same as the distal waist length.

24. The balloon catheter of claim 23, wherein the tie layer includes low density polyethylene.

25. The balloon catheter of claim 23, wherein the tie layer is heat-shrunk onto the inner tubular member.

26. The balloon catheter of claim 23, wherein the tie layer is multi-layered.

27. The balloon catheter of claim 23, wherein the inner tubular member includes polyethylene and wherein the tie layer has a relatively high bonding affinity for polyethylene.

28. The balloon catheter of claim 23, wherein the inner tubular member includes polytetrafluoroethylene and wherein the tie layer has a relatively high bonding affinity for polytetrafluoroethylene.

29. A balloon catheter, comprising:
a first tubular member having a distal end region;
a second tubular member disposed within the first tubular member, the second tubular member having a distal end region that extends distally from the distal end region of the first tubular member;
a balloon having a proximal portion and a distal portion, the proximal portion being attached to the distal end region of the first tubular member and the distal portion being attached to the distal end region of the second tubular member;
wherein the distal portion of the balloon defines a distal waist having a distal waist length; and
a tie layer insert disposed between and thermally bonded to both the distal waist of the balloon and the distal end region of the second tubular member, the tie layer insert having a length that is substantially the same as the distal waist length.
30. The balloon catheter of claim 29, wherein the tie layer insert includes low density polyethylene.
31. The balloon catheter of claim 29, wherein the tie layer insert is heat-shrunk onto the second tubular member.
32. The balloon catheter of claim 29, wherein the tie layer insert includes a plurality of layers.
33. The balloon catheter of claim 29, wherein the second tubular member includes polyethylene and wherein the tie layer has a relatively high bonding affinity for polyethylene.
34. The balloon catheter of claim 29, wherein the second tubular member includes polytetrafluoroethylene and wherein the tie layer has a relatively high bonding affinity for polytetrafluoroethylene.

35. A balloon catheter, comprising:

an outer tubular member having a distal end region;

an inner tubular member disposed within the outer tubular member, the inner tubular member having a distal end region that extends distally from the distal end region of the outer tubular member;

a balloon having a proximal portion and a distal portion having a length, the proximal portion being attached to the distal end region of the outer tubular member and the distal portion being attached to the distal end region of the inner tubular member; and

a multi-layer insert disposed between the distal portion of the balloon and the distal end region of the inner tubular member, the multi-layer insert having a length that is substantially the same as the length of the distal portion of the balloon.

36. A method for bonding a balloon to a catheter shaft, the method comprising the steps of:

providing a catheter shaft, the catheter shaft including an outer tubular member with a distal end region and an inner tubular member disposed within the outer tubular member, the inner tubular member having a distal end region that extends distally from the distal end region of the outer tubular member;

providing a tie layer having a length;

thermally bonding the tie layer onto a portion of the distal end region of the inner tubular member;

providing a balloon having a proximal waist, a distal waist, and an expandable region therebetween, the distal waist having a length that is substantially the same as the length of the tie layer; and

affixing the distal waist of the balloon to tie layer.

37. The method of claim 36, wherein the step of thermally bonding the tie layer onto a portion of the distal end region of the inner tubular member includes heat shrinking the tie layer onto a portion of the distal end region of the inner tubular member.

38. The method of claim 36, wherein the step of affixing the distal waist of the balloon to tie layer includes thermally bonding the distal waist of the balloon to the tie layer.